STATE OF MARYLAND

ADVISORY COUNCIL ON PRESCRIPTION DRUG MONITORING

HOWARD COUNTY HEALTH DEPARTMENT

7178 COLUMBIA GATEWAY DRIVE

COLUMBIA, MARYLAND 21046

JUNE 5, 2009

9:30 a.m.

BEFORE THE HONORABLE JOHN F. FADER, II, Chairman

ATTORNEY GENERAL CURRAN

CAROLYN QUATTROCKI

DR. HOWARD HEIT, MD, FACP, FASAM

AARON M. GILSON, MS, MSSW, PhD

MS. LISA SPOFFORD

Reported by: Monica A. Sienkiewicz

ALSO IN ATTENDANCE:

DR. J. RAMSAY FARHA

ALAN FRIEDMAN

DR. ROBERT L. LYLES, JR.

GEORGETTE ZOLTANI

SHIRLEY DEVARIS

DR. MARCIA WOLF

LINDA BETHMAN

DONALD TAYLOR

JOHN MOONEY

DR. NICHOLETTE MARTIN-DAVIS

MICHAEL WAJDA

PHIL MILLER

JOHN STANT, JR.

KAREN THOMPSON

MANDY DAVID

LARAI FORREST

GWENN HERMAN on behalf of DR. BETH MURINSON, MD

GAIL KATZ

(OTHERS IN ATTENDANCE ARRIVING AT VARIOUS TIMES.)

P R O C E E D I N G S

WHEREUPON --

JUDGE FADER: We have a new court reporter with us today. I have known Monica since she worked in the jury office at the Circuit Court for Baltimore County. Monica, you were not bashful then, so don't be bashful now. Please ask anyone to identify themselves and they can shout it out because it is important to get down exactly who is talking about who.

The University of Maryland School of Law has graciously consented to give us a research assistant and pay for that and one of our students, John Stant, please stand to let everybody see, is going to be working with us for all of this. He is interested in this field. He is one of our students at the University of Maryland School of Law. His father is a pharmacist and he is just generally interested in the field. We are very much looking forward as we go forward now to put all these statutes together as we go over the next couple of months and say this is that topic or this topic and this is how this state has dealt with this and then of course eventually down the road we will be taking a

vote as to what our recommendation will be where majority and minority positions will be set forth for the legislature in footnotes and end notes and things of that sort to consider. The next meeting is July 17th and that will be the prime meeting for the set up as to how we are going to proceed with this generally and John is going to help with that. Is there anyone else here who is new?

MS. DEVARIS: I am taking Nancy Adams' place. I am Shirley DeVaris.

JUDGE FADER: Does anybody else want to stand up and tell us who you are?

DR. HEIT: My name is Dr. Heit. I am a practitioner in Northern Virginia and in my talk I will go over my patient population.

JUDGE FADER: I mean people other than the speakers, excuse me, that is my fault because we will introduce you a little later.

This is the guy that signs my license to practice pharmacy, although he is so nice he could call up and say now we are giving you this license on the condition that you promise you won't practice pharmacy, but he has never done

that. He would be right if he said that. I renew my license because I am very proud of being a pharmacist but I would be so dangerous out there. Please identify yourself.

MR. TAYLOR: We appreciate your contribution for the cause. I am Don Taylor, the President of the Board of Pharmacy.

JUDGE FADER: The gentleman to my right, all of us have known for many, many years. I always remind Joe Curran, General Curran that three or four days before he became Lieutenant Governor he tried his last jury case before me. He won it. He was a great lawyer when he practiced, terrific. He's a great lawyer for the State of Maryland, our Lieutenant Governor, Attorney General, for so many distinguished years and with this project he was the one, the catalyst, along with Carolyn that got this started, that realized with everyone involved here that something needed to be done. He was the one that propelled it forward. We are going to listen to his history and what he encountered and where he is with regard to all of this.

Carolyn Quattrocki is with the Office of the Governor now. She says she is a little less tired then she

was during the legislative session. We are very, very glad to have both of you here to tell us about this project that you started and the two of you put forward. We don't have any bashful people here and I am sure there is going to be a lot of questions. Thank you for coming.

GENERAL CURRAN: Thank you very much, Judge and members of the commission for permitting me to stop by this morning and to chat with you a little bit about this issue. Carolyn Quattrocki is currently serving on the staff of the governor's office working on litigation was for a period of almost twenty years or a little bit more than twenty years in the Office of the Attorney General, while I was there, in the very important civil litigation unit but also served as a special assistant on a series of very important issues that we dealt with. She was one of our top people in the office. We are here to answer any questions you might have.

I will give you the briefest background of why I even get involved in this issue to start with and what I know about it. I took a phone call back in I think 2000 from then Attorney General of Virginia, a fellow by the name of Mark Early, who I had come to know and respect on a

couple of different issues that we worked on at the National Association of Attorney Generals meetings. Mark asked me to meet with him and others in Richmond at a time convenient to discuss a problem that he believed Virginians were having in the southwestern section of Virginia. Sheriffs, law enforcement persons and medical people were calling the State and saying we have a problem and they wanted to talk about it. It turned out that I did go to Richmond and met with Mark and a number of law enforcement people and other medical people to talk about the issue of a number of pharmacy break-ins and doctor office break-ins and a number of instances alleged of doctor shopping or doing whatever it takes to get Oxycontin in the southwestern section of Virginia in the late '90's and early 2000 and something was going on and they didn't know what to do about it because there seemed to be a big supply of this issue. There was an indication that many of the folks in that area from southwestern Virginia and Kentucky had received injuries, Worker's Comp type injuries, perhaps, in the coal mines and other industries down there and were obtaining a very wonderful drug for appropriate pain relief prescribed by a

physician for the right condition and it did work quite well. That is when I heard about it for the first time.

Mark and I decided to bring it up to the attention of the National Association of Attorney Generals when we next met again and the then Attorney General, Jay Pappard of Pennsylvania, said I have the same problem in Pennsylvania. We are hearing about this issue. I tried to determine what was the record in Maryland and it didn't come to the tip of the iceberg that it had been coming in in Virginia and Pennsylvania.

I learned about this drug the Purdue Pharma had on the market and a time-released type of pain medication and it was working very well according to the physicians we talked to for persons who had severe pain or cancer or rheumatoid arthritis or any other type of pain that needed medical attention.

So then we decided, let's talk to the folks and see what is going on. We did have meetings in Washington and several leader persons from a Connecticut firm came down and talked to us and yes they were -- they thought this was a wonderful drug and working well and we were trying to get it

widely distributed so it could be beneficial to those who needed its help, but it wasn't some salesperson going to every doc that they could find. They were trying to be judicious in who they were urging to consider their product. That is when I really first learned about this issue.

Now, again, I don't wish to suggest something that is not there but it was inferred by some of the officials at the National Association of Attorney Generals and some of the law enforcement people that perhaps there was an effort to really get this new, wonderful drug widely distributed, perhaps, more widely distributed than would be appropriate. Again, this is alleged that if it had gone to the recognized pain management docs that they would have a better understanding of how this is controlled, rather than perhaps someone who is not quite as up to speed with how to manage pain. That was the inference. Obviously that was denied but nonetheless I am telling you that is what was inferred.

So we continued to talk about this at different meetings and then we were hearing from other law enforcement personnel that there were instances that Emergency Rooms in our state and other states were finding that overdoses from

prescription medication was extremely high in Emergency Rooms, higher than some of the other drugs we know about, heroin or cocaine, but that Oxycontin was up there quite high and it seemed that there was pain relief for some but the inference being that it was also some ability to get these drugs for nonmedical purposes and also the information from the police is that if you got a thirty day supply of this, the pills are quite lucrative on the street, and that gave them some concern and also gave us some concern because what do we do about it.

On the one hand, this is a valuable tool for the medical people and an extremely valuable tool for people who are suffering from chronic pain and yet there may well be and probably are some people misusing and abusing it and what do we do about it. This is what came to my attention. Then it began to be suggested at the national level that there be a study state by state to see what are the problems across the nation, not just Virginia, Pennsylvania and Maryland. And it seemed that more and more states were saying yes, there is some problem and maybe there should be some mechanism to find out how we can identify those few

persons who are not doing as they should, whether they be physicians or more than likely whether they be people who are trying to abuse drugs. How do we do that and how can we monitor -- where do they come from, there's a prescriber and a dispenser. What is the best way to do it and that is what the discussion was all about.

There did come a time when there were I suppose genuine concerns that reached us about the activities of the DEA and whether the DEA was taking appropriate action, were they maybe -- again, this is the allegation. Are they heavy-handed, are they really looking at a lot of doctors, are they looking everywhere to see some misconduct.

I think we got involved because there was an instance of a doctor in Northern Virginia, whose name escapes me for now, but apparently had in fact been the target of or subject of an investigation by the Feds and he did receive a sentence. I am told by the medical people that sent a bit of a chill through the medical community, look what happened to so and so and he was a pain person and we are now concerned about this.

So several of us at the national level decided to

visit the DEA office in Washington. I did go to the then administrator person and say we have a problem here. On the one hand you have to do your job and we have to do our job, but we have people who have chronic pain, a lot of people have chronic pain for a variety of medical issues and one of the ways of relieving this constant pain is to see the appropriate medical personnel and have them monitor and prescribe the appropriate medicines. So you can on the one hand try to be stopping some people from robbing pharmacies and robbing doctor's offices and taking scripts from doctor's offices and trying to pass them off at various CVS's and Rite-Aid, that is one issue. But at the same time, you have the issue of doctors who day in and day out giving help to people who need help. There has to be a balance. That was our message. I can simply tell you, those of you who are medical personnel, we got a very, very sympathetic ear from the DEA people. They understood that and they rationalized we can do our job but at the same time we don't want to stop they, them, from doing their job and that is why we work with these monitoring programs. That was my background in this, to try to find out what the

problem was, heard what the problems were, know there are two sides to the story and try to bring it to the attention of the state government people, this is what we know, we learned this.

As such, after more reading and with the help of Carolyn, a lot of reading, we decided to address the issue in Maryland and found out well, we just don't put pen to paper and start copying something. You say let's meet with Med Chi, what is the issue from your standpoint, you have to meet with the pain doctors, let's meet with the pain doctors. Tell us about your issue, let's meet with the pharmacists and the drug companies, let's meet with anybody else --

MS. QUATTROCKI: The patients.

GENERAL CURRAN: -- in order to do something right and fair, you just can't say, well hey, guess what, there is some misconduct going on, there are a lot of issues involved. We took a long, long time meeting again and again in our office in Med Chi's place, wherever the pain people wanted to meet and say here is the issue, what do you think, look what is going on in Kentucky and Virginia, and look

what is going on here and look what is going on at the national level. They are trying to encourage all fifty states to have some monitoring program and that there are some funds available, maybe not as much as we might like but there are different grants available to do this, please consider this. We want to consider it.

Then we started seeing a series of states, and I think it is somewhere in the high thirties right now, that have a program. There are different kinds of programs, but it is not like it is just Virginia anymore. It's up in the high thirties and they're urging that it continue for the last twelve, including of course our state, and what was concerning me is that if there was some truth to this ability to try to misuse these drugs if surrounding states to Maryland had a program and Maryland didn't, that became somewhat attractive. The only reason I say that is because I did talk to some folks down in Kentucky that have a rather ambitious program and I learned that just a couple of weeks ago the Lieutenant Governor of Kentucky wrote to the Governor of Virginia saying that he, the Kentucky Lieutenant Governor -- pardon me, that Florida had passed a law and he

would hope that the Florida Governor would sign the law because they had instances of Kentuckians who are on a list in Kentucky that have been motoring down to Florida and seeing pharmacies and/or doctors in Florida getting prescriptions they are not able to get in Kentucky and he thought if possible they would share with Florida their software to show that they can compare notes.

All I know of one state asking this, so there is some effort by Kentucky to share software with Florida because of their concerns. The Kentucky person led me to believe the software from various states could be shared because if you live in Hagerstown it's easy to go to Pennsylvania or West Virginia or if you are in Denton, you can get over to Delaware. So that is really where we are at.

The point I would end on is the report that we wrote was really an invitation to all sides to say hey, here is all of the information we got and we ended up putting it in a bill and if you read the bill, I thought -- and I know you have, but when you read the bill or as you read the bill you will see an effort was made to say let's be inclusive

and let's have the State Health Department have these advisory groups and these groups that would be as fair as they can be and that is essentially where we came from. I don't mind telling you I was a little bit surprised when the bill was vetoed. All of the work we did, I mean come on. He didn't even tell me which is a bit of an issue, too, anyway we put a lot of work in it. It wasn't something done overnight. It was a couple of years of work at the national level and listening to what other states were doing and simply trying to suggest that our state, which is a very good state, have a similar type of program where we can protect the interest of the people who are doing great medical work and help the individuals who need the help of the physician, but at the same time, try to make it more difficult, if not impossible, for those who are abusing the drugs and doing things they should not be doing and causing great harm to people who are addicted to this.

JUDGE FADER: Carolyn, do you have a copy of the report there? Can you do me a favor and hold that up and show that to everyone. Now we did send a copy of this to everyone. What is the report titled, Carolyn?

MS. QUATTROCKI: Prescription for Disaster.

JUDGE FADER: Prescription for Disaster. If anyone misplaced your copy or feels you didn't get it or somebody here wants it, just send to Georgette an e-mail and she will send you a copy in PDF for that. We also urge everyone here to put yourself on our e-mail list. Once you sign up for this, we do everything by e-mail and you will get a copy of everything that goes out to everyone. We are going to sign General Curran and Ms. Quattrocki up for e-mail, whether they want it or not. So we hope when they see things coming across their desk that they can give us the benefit of their advice.

GENERAL CURRAN: I will end by saying, was this going to impose some -- an unrealistic burden on doctors, on pharmacists, on drug suppliers, on DHMH, is this a burden that hey is just too big and we should let happen what happens and let it go along. Of course we do know that much of this information is now known. When I go to my neighborhood pharmacy to get my medications and I have an account with Blue Cross/Blue Shield, my name is entered and I am getting my X, Y, Z medications and it is approved

happily from the insurance company that I've ran out of my pills for this month and I can have another supply. So the information is already there about the medication I am getting through prescriptions or if I am a Medicaid person, the pharmacist double checks and gets a payment from Medicaid so the State Department has information that I am a Medicaid patient and I need X, Y, Z prescriptions filled, so Medicaid has that information.

I might add, the Medicaid Fraud Unit at the Attorney General's Office that we have had since 1979, does in fact periodically have a chance to get information from the Medicaid system people as to what appears to be a problem. That is how sometimes the Attorney General's Office in a Medicaid issue deals with a violation of the Medicaid program by either a dispenser or a medical person or a recipient. So it is happening now from time-to-time in the Medicaid program.

I might add, we are very careful when we check these things out because there's a flip doesn't mean ah-hah. I can assure you that people aren't in the business of willy-nilly, you make darn sure there is something to

investigate. The point I am making that it is going on now. Now I will admit if a fellow comes in with a script and he gives a hundred dollar bill, it's a cash transaction --

JUDGE FADER: I think you will find out from this group, that is one of the problems. A very great percentage of the people abusing these drugs are paying cash. And one of the things that is going to bring about is a decision by the political people in the State of Maryland as to whether or not there's a requirement for an identity card. We are a liberal, democratic state who has -- and liberal democrats have avoided any type of an identity card and that is going to be one of the questions that the legislature is going to have to do deal with, probably not so much a problem now because of all these drivers licenses and things like that. This is going to be a big political problem and we are not asking you to guess as to how that is going to turn out --

GENERAL CURRAN: I was aware of the cash issue and Medicaid issue and the Blue Cross/Blue Shield issue. It is not something that we did not understand. We realize that was an issue and a problem. It is, though, that when that abuser person is going to the CVS he does have a script and

a hundred dollar bill. The question is then what do you do about that? Do you call the doctor, Dr. Jones, Joe Curran is here for Oxycontin, did you prescribe that? I don't know how that is answered but I am saying that --

JUDGE FADER: We tell -- I teach the pharmacy law program at the University of Maryland School of Pharmacy and we tell our pharmacy student if you don't know this patient and you don't call, you are due every problem that is going to come your way from the Board of Pharmacy because that is just stupid not to do that. I think the pharmacists are pretty well educated that that needs to be done. I know you keep telling me you couldn't have done it without Carolyn.

GENERAL CURRAN: Carolyn, please walk these folks through the series of meetings we attended for hours on end trying really to find out are we on the right page, and if we are not, get us on the right page. What is your recollection of our efforts?

MS. QUATTROCKI: Thank you for the opportunity to be here with the Attorney General. I was trying to think about how I would supplement what the Attorney General would say in a way that would be useful for you all today. I

guess I will open by saying that there was work on a lot of issues with General Curran but this may have been the one where I appreciated the most his very well-known approach to everything which is to be balanced and inclusive and fair. You didn't have to get very far into this issue without realizing how many different kinds of conflicting really important interests and agendas had to be reconciled.

So as the Attorney General said, we started out with a completely open mind and he met with everyone that could possibly have an interest in this. I remember those meetings, some in his conference room with the pharmacists and the pharmacies and the retail pharmacies and the independent pharmacies and the doctors and then we went to the pain advocates to talk to them and the law enforcement folk. We had working with us at the time, Jack Schwartz --

JUDGE FADER: Jack Schwartz is now down at our plant. He is one of the most valuable members of our adjunct.

MS. QUATTROCKI: He came at this with a vast background in palliative care and end of life care and pain management, so he made sure that we had an appropriate focus

on that component of this conundrum.

So the report, I think, when you read it, reflects that because it opens with a recognition that let's start not with the fact that this is a huge problem, prescription drug abuse, which it is, and if anything is now worse many years later, but that there's a big problem with pain management and under prescribing of pain killers for people who suffer from chronic pain and that prescription drug abuse was actually feeding that problem. I think this is something that it would be helpful for all of you to keep in mind as you craft this, that you can make the case that a prescription drug monitoring program will have a chilling effect on effective pain management because doctors will be afraid of increased prosecution. At the same time, though, the fear is out there already. There are studies cited in this report where doctors talk about already under prescribing for pain because of this fear of prosecution. I think if you all can do this right, you can actually help the problem of under prescription and access to effective pain management. If you do it right, then doctors will begin to have more confidence that prosecution will be

appropriate and targeted at the right folks and not the wrong folks as well as using the monitoring program for people who are addicted to the drugs.

So the Attorney General started out by talking about all of these folks and I will quickly -- I would be happy to answer any questions but I will quickly take you through the process of enacting the bill. I think it can be instructive as to you all in now trying to make your recommendations.

We talked to the National Alliance for Model State Drug Laws and they, at the time and I believe they still do, had a model statute. We took that model statute and then after all of these meetings with all of these stakeholders modified it significantly to make it -- the statute itself more balanced and to make sure that the actual -- again, this is one of those exercises where you learn the details, that the actual language of the bill reflected -- the primary concern which was to say this would be a balanced program, that would have as much attention to facilitating access to pain medication and effective pain management as it would to helping law enforcement and prosecute drug

aversion and then helping doctors identify abusers. So for example, when we looked at what other states were doing at the time, some number of states had the prescription drug monitoring program housed in a law enforcement agency, whether it would be the Attorney General's Office or a State's Attorney Office or some other equivalent. Others had it housed in the Health Department and we chose the Health Department for obvious reasons. Those being an example of the judgments made along the way to make sure it was balanced.

Then we crafted a bill that we thought was balanced and then what happened, and I would encourage you -- I have a memory so I can barely remember what I did last week let alone what I did four years ago. So when I was going back to try and remember what we did and get steeped in the issue again, if you go and look at the bill that passed, you will see the changes from the original bill as we put it in which already was a change from the model law request what we hoped to be a more balanced approach and then you will see the changes the General Assembly made and you can see the flash points. Judge Fader sent me some of the transcripts

of people who have come and talked already and I think you all are grappling with all of the same issues that we grappled with then and the General Assembly. Then for example, the issue of what drugs should be covered and some might say it would be helpful from a health care point of view to have all drugs covered. On the other hand, then there's a fear and so some states have only schedules four and five or whatever it is. I am forgetting the numbers, but at the time we had schedules two through five, I think, then we wanted to put in language about being able to add drugs of concern through regulation. The thought being that the good news is new prescription drugs are coming on the market all of the time and there ought to be a mechanism without going back to General Assembly or going back to change the schedule and add drugs. The General Assembly did not like that. They wanted more control. Part of what I am talking about now is political but it is also substantive. That is one of the questions, what should the coverage be and giving that much leeway to change the drugs that would be covered was something that politically people weren't comfortable with and maybe that informs a substantive

judgment, too.

Another example, and this is a huge issue and I know from reading the transcript you all already are addressing it. The appropriate use of this data and who should get access to it and under what circumstances and for what purposes. You will see when you look at the bill that, you know, we wanted -- it was our judgment that doctors should have access and the patient, himself or herself, should have access and the hot button question, what law enforcement personnel and under what circumstances.

So it was a big debate and on one side some law enforcement personnel told us that a really important thing is to be able to look through the data to look for patterns. You can see patterns show up in the data. We ultimately made the judgment and the General Assembly made the judgment that no, that is too close to a fishing expedition and that will feed the fears this will be this witch-hunt prosecution effort going on. So the bill ultimately very specifically says that law enforcement gets access to the data, only to supplement an ongoing bonafide investigation. In other words, they had to get information about a problem from some

other source before they can then have access to the data. That is another example.

You will see in the bill there were concerns about costs, the pharmacists and pharmacies wanted us to put in language that made it clear there would not be any extra costs imposed on them. I think things that have evolved since then with health IT and the electronic health record so I am sure -- I think even the last meeting you had someone from the health care commission talk about where we are going in the state with health IT and electronic records. One of your challenges is to figure out how your efforts dovetailed and tracks the state as it evolved in that regard. You don't want a situation where you created a program and can't talk to whatever system we end up having with electronic health records, generally.

So costs and burden, administrative burden and time management for pharmacies and pharmacists was an issue. There was an issue about liability and you will see in the bill the bill was changed to add language making sure that a pharmacist or a doctor would not be able to be held liable for a failure to affirmatively act on information he or she

should have had access to or should have reported or should have checked or whatever. Again, another example of trying to thread the needle.

The last example I will talk about from skimming the transcripts, I wish I had more time, but Judge Fader, I think you were talking about the issue of what kind of direction or advice or -- control is too strong a word, do we want to put on law enforcement in terms of their use of this data to prosecute?

JUDGE FADER: Let me stop you there and say Dr. Farha, who is the secretary of the board of physicians will tell you they have already disciplined some physicians for taking access, generally, when they had no right to. So this is going to be a concern for law enforcement and for the physicians and the pharmacists but they have had disciplinary procedures -- Don, have we had any for the board?

MR. TAYLOR: No.

JUDGE FADER: Not at this point. Physicians getting online and getting access, they had no right to do that and they have been disciplined. I did not mean to

interrupt you but that is a pretty important part of this.

MS. QUATTROCKI: That is an issue on both sides for sure. I was going to make a final point that an addition that we developed and put in a bill that was different from the model statute -- I don't know if you all have, but it really looks closely at the bill, yet, we provided for the creation of what we called the multidisciplinary consultation team. It was to be made up of staff of the program, folks running the program, usually from the Health Department and then a smaller subset of representative stakeholders, pain advocates, pain management doctors and medical personnel that would serve in an advisory capacity to any law enforcement personnel that would receive access to this data for whatever case they were investigating.

The thought there was, and this goes to my initial point about if you do this right you could actually increase physicians' comfort level with the kind of enforcement going on. Right now, you have a situation where law enforcement is sort of out there on its own doing its own thing, without necessarily very much education or expertise about pain management and what kinds of prescribing patterns, evolving

standards of care, that was another thought behind this multidisciplinary consultation team, that this medical team, they would be the ones that would keep up with evolving standards of care with respect to prescribing and pain management. They would serve then to inform and advise the use of this data on the part of law enforcement.

There are different -- I am sure there are other ideals out there about how to address that particular problem --

JUDGE FADER: That was one of the main things that came up with the consideration of will there be a procedure set in place that requires the law enforcement personnel to consult with the pain people to find out whether or not this is a viable treatment plan. Now some people here, I know want a program where the law enforcement people have to abide by the decision, but the Constitution of the State of Maryland says that is prosecutorial discretion so the most I told them they will be able to do, that is going to be a very important part because there are physicians in this room, specialists in this area, who could not go into a hospital and resection a bowel or things of that sort

because it is out of their field. We need the law enforcement people to understand there are people that can say this is a viable treatment program.

MS. QUATTROCKI: And that is how we thread the needle in this bill. You are right. You can't have a consultation team directing the prosecutorial decision. You can require the consultation and the advisory role and we felt that was really important. I guess to that point, I would close and be happy to answer any questions with the Attorney General, that as you are going through this, I guess I would bear in mind that you don't want to let the concerns about -- it's clearly a huge problem and it needs to be addressed and thirty-eight states have done it in some fashion, so you are not operating on a clean slate and the world hasn't fallen apart presumably in these other thirty-eight states.

I will mention the worksite fraud act where some of the same concerns of enforcement of the law and what is the violation and how do you define it and how do you make sure that people aren't prosecuted wrongfully and that law enforcement isn't going to go after people and even if in

the end they are exonerated they have to go through the horror of the investigation and I know that is a real fear on the part of these physicians.

JUDGE FADER: Then they hire a lawyer and two or three years later, they say we are not going to prosecute you, you have done nothing wrong. Then they say, who is going to pay this forty thousand dollar bill for my attorney and that is also a very big problem.

MS. QUATTROCKI: Again, I would urge you to really think carefully about how to craft the consultation team concept, whatever you do to inform the enforcement but to bear in mind, you absolutely in crafting this law, have to pay attention to the edges. You have to craft it so you take care of as best you can the gray area cases. The cases around the edges that are hard. Bear in mind, also, the vast majority are going to be clear and you are going to get law enforcement -- they have limited resources and limited personnel. They have no interest, not to say they don't make mistakes and not to say you don't get the bad apple out there, but institutionally, they don't have an interest in wasting their time and resources on the peripheral cases.

We've bumped up against this in the workplace fraud. When you get all these people arguing in the committee hearing what about this and what about that, then you talk to them privately and they are like everybody knows what this is, it's clear when you get out there and dealing with it, people know what it is and the gray areas are the rare exceptions. I am sure you are talking to people that no way more than I may sense when we talk to folks most of these diversion and abuse cases are pretty clear. You do have to pay attention to the gray areas, but you don't want to get -- you don't want to throw out the baby with the bath water is what I am saying.

JUDGE FADER: Does anyone have any questions or comments?

DR. FARHA: Thank you very much for coming and giving us that perspective. Probably it is time for me to talk a little bit about some of the concerns we have. The major concern we have was the front and center of this problem, was a hundred percent totally excluded from all of your deliberations and meetings, which is the committee of addiction medicine. We had absolutely no input, no

representation, no clue of all of the stuff going on until the HR. There was no representation either in the bill or any step of the way of the most critical part in this. As you know, the major problem with addiction medicine is diversion, illegal use, an inappropriate misdiagnosis that leads to the problem by inappropriate treatment and the lack of screening of patients that need to be screened before any medication is properly given and on and on. We had zero input. So you end up with a product that is missing a very critical part of successful implementation and outcome.

We tried at the very last minute, there is no one from addiction medicine in the statute, in the deliberation working on this process. How can that be? The issue is an addiction medicine issue and there is nobody.

Problem number two is -- I very much appreciate all of the things you looked for and surely there's a difference from Pennsylvania being a strictly criminal investigation with no -- a hundred percent medical investigation with no criminal. Obviously, it was all over the place, thirty-two states with programs, none of them are the same, six states with legislation all over the place and the common law makes

sense and I really appreciate your efforts in modifying the common law that Mrs. Green put together.

The critical balance is exactly what you are saying but after it is all said and done you want to have a product that is functional and serves the purpose which is worth spending the money to do and sometimes when you see these laws and the little thing that is hampering the progress so much so, it is pretty much about seven or eight states that have to go back and change the law to make sense because what they have is obsolete and disfunctional. The delay that has occurred has surfaced because now we have learned from all of these different states of what not to put in the law. All of the hampering of the procedures, certain law limits a kind of software. I am very optimistic we will have a functional piece because we have the education and now we have the input from the advisory board which we did not have before in looking at the issues from an outcome standpoint rather than from a process standpoint.

I wanted to tell you we have a good product but is missing the critical element and this serves the purpose of being able to study it, put it in a better perspective,

justify why we put in all that money and this is going to cost and someone is going to pay for it. Even when we get the grants and I have all the information on how to get the grants and I am optimistic about that, how are we going to keep it up year after year and if we don't do it right, two or three years from now why say did we spend all of these millions of dollars, show me proof, forget you guys, we are not going to do it anymore. So you put all of this effort in something that is not going to give you what you are looking for.

So this is my quick comment on the historic perspective and I guess you didn't realize addiction was part of the problem.

MS. QUATTROCKI: On behalf of the Attorney General, we would certainly apologize. We really were trying so hard at the time to think about all of the different people that we should be talking to. I will point out though, that in establishing the advisory board in the bill we had provided that there would be four physicians and one nurse practitioner with expertise in areas of practice that involved pain management and substance abuse and addiction

treatment. So we weren't totally clueless.

DR. LYLES: I don't remember excluding addiction medicine. I thought Med Chi was as inclusive as it could possibly be. Why we didn't have someone such as yourself in the meetings with Attorney General Curran and Carolyn, I don't know that. Maybe it was an oversight. Pain management was there. We had practically everyone we thought would have an interest.

DR. WOLF: We went out of our way to broadcast the meetings. I do remember, however, that I got a call on a Thursday or Friday and the meeting was on a Monday or Tuesday. It was a very, very short window.

DR. LYLES: We have this difficulty with State agencies all the time. They call a meeting at lunchtime right in the middle of practice and sometimes you can come and sometime you can't.

GENERAL CURRAN: Thank you for your comments. All I can say is I assure you there was a genuine effort to make sure that we had, as they politically talk about the big tent. We wanted the biggest tent you could get and if someone was left out, it was our mistake. We didn't read

the signals right. Certainly, going a bit slower and getting the best from what is in the thirty-two states or thirty-eight states, seeing where state A made the mistake or state B did a good job, that will clearly have a better product.

All I know is I got a phone call six or seven years ago from someone concerned about something down in Bristol, Tennessee and that is what led to this.

DR. FARHA: I am very happy to be a part of this and that we are moving and studying and trying to come up with the best possible outcome.

I want to make a very quick comment on the data and data analysis. This is very critical. A lot of people look at patterns and data. If you are not savvy in looking at that information, you can make some very dangerous remarks. The advisory committee is to analyze data and look at data and talk about the effects.

You have talked about the chilling effect and the studies have shown so far that the states where they have had programs or laws that have already had a drop of twenty percent in prescription writing units of drug writing for

pain killers. However, in studies had a fifty percent of mortality from overdose. So when you are looking at chilling effects, you need to know how you are looking at them and how you are interpreting them. There is so much detail and the difference between the different stages is it is easy to go on a slippery slope. I felt the advisory committee should be much stronger and more defined and much more specific in expertise and have a higher level of accountability. People who are paid to do this and be the consultant for the action, rather than look at this or look at that. It has a power. More importantly, is what data you are going to collect and how it is going to be looked at. Combinations of certain medications lead to death and if you don't have an opportunity and you are spending all of this time and money, you should have the patient's safety and interest, we would have missed a tremendous opportunity. To only use this for prosecution is a waste of resource.

JUDGE FADER: Let me say this now, we are twenty-three minutes of eleven o'clock. We have a few more minutes until fifteen minutes of eleven for anyone else who has comments and then we have to continue with the remainder

of our program. So if anyone else has any questions or comments of General Curran or Ms. Quattrocki?

MR. FRIEDMAN: Good morning, Alan Friedman with Kaiser Permanente. Thank you both for your historical perspective with what is happening in other states and also what has happened with the bill over time. In that vein, you asked about the burden on physicians and Dr. Farha addressed some of that. From the pharmacy perspective, an independent pharmacist, they would have to have a system that supports data capture and transmission to the state. That may not be a problem if they have an independent pharmacy only in one jurisdiction. But for large community pharmacies or in multiple jurisdictions, I think it is important that we be able to pull together data and transmit the same way within multiple jurisdictions. D.C., for example, does not have a law around drug monitoring program yet but I was in a meeting yesterday with the Board of Pharmacy and they are now beginning to engage the conversations around that.

I do want to make you aware delegates from the member boards of pharmacy two weeks ago met at their annual

meeting and one factor was to develop standards for prescription drug monitoring programs. I don't know what will come of that and of course whatever they pass, those are only recommendations for state board and pharmacies. They can choose to adopt them or not. I think it is worth looking at and I can send to Georgette the full text of those resolutions and we can all be aware of what those are as we are moving forward.

JUDGE FADER: I am going to ask both General Curran and Carolyn Quattrocki to put their e-mails here so we can send you all of this additional information. I can only say Alan, my friend, my old fifth grade teacher, Sister Rita Gertrude, would never appreciate your handwriting.

Don, how about putting your e-mail there, too. Any other questions from anybody? General Curran and Carolyn Quattrocki, thank you both very, very much. We hope that both of you have the time and will take the time to help us. Carolyn, can I see that bill?

MS. QUATTROCKI: Sure.

JUDGE FADER: To start this and to drive it on and to please let us have the benefit of your comments as you

see things that are coming through, of course, you will each get a copy of this transcript, as everyone will. I think these transcripts are very helpful. This is something I have very much wanted to do to have people go back on all of this. Anyone else? We can tell these people they can certainly stay and we'd love to have them. We are going to listen to the people that deal with pain or go out and play in the rain.

GENERAL CURRAN: I will end with this one thought, Your Honor. Judge, you sat in the Circuit Court for Baltimore County for a number of years and heard case after case after case brought before you by the State's Attorney office. I spent twenty years -- twenty-five years practicing law, twenty years in the Attorney General's Office and I can just tell you from my observations, I never found a prosecutor, state or federal and certainly not in the AG's Office who was anxious to proceed where there wasn't some justification. I guess I say that because I just wanted to downplay the idea that I thought was in the minds of some folks when we went through the DEA and their prosecutor and were doing things that your sworn prosecutor

should not do. It has simply been my experience that that doesn't happen. You might say well I know about something and maybe you do. I am just telling you I spent twenty-three years practicing law and twenty years in the AG's Office and I can tell you we were very religious in making certain that if someone believed something was wrong, we never did a thing unless we knew it was wrong and could prove it was wrong.

I would like to say that I don't want anybody to think that I believe that prosecutors will just misuse this. I don't think that is the case. I have been around long enough to know I never saw it and if it happened, it was so rare as to -- anyway, that is an observation I had from a lot of years. Judge, you've tried a lot of cases --

JUDGE FADER: I've listened to a lot of pharmacists and a lot of physicians and it is certainly true that most of the excesses that I saw were on DEA's part where they moved in and take everything. I saw -- refused to sign a number of warrants for prosecutors that wanted to take all of the data, the computers and things like that out of an office, that would not leave anybody access to any data, so

yes, I did see some states and refused some state overtures and refused to sign warrants when people would want to come in and clean out a pharmacy and not leave anything so Marcia's husband could get his prescription filled. There weren't many, but I did see some things, so I do believe that although rare, that this ability of the state people to overdo and become overzealous. I remember sitting there and saying to a couple of them, well are you going to leave them a disk? Why do we have to leave a disk? How are the people going to get refills for prescriptions. Now that is not as much of a problem today because at two o'clock in the morning, they load all and they keep a copy in someplace in the desert in Nevada, but all of these things have been very real problems with some of the prosecutorial things over the years and we have to deal with that.

DR. LYLES: At a previous meeting, I passed something onto the judge from the Virginia Board of Medicine. After this was fully implemented in Virginia, I went through and counted the number of cases associated with so-called schedule two. We have never had that many in Maryland in a quarter. I just can't imagine that many

surfacing, but in Virginia it did.

Now I don't know if those are real. I didn't look at the elements of the case, but there is something there that seems amiss and when I am as a physician get that publication from the board that could affect my license in Virginia that does have a chilling effect. Was it a one-time sort of situation?

JUDGE FADER: With that, we are going to move on. See, this is the problem when a judge is in control of this. I don't want to hear anymore. You heard that quite a few times.

GENERAL CURRAN: He was a very fair judge, though but firm.

JUDGE FADER: Thank you both. Gail and Gwen, if you could come up here. We can take a break and after that we listen to our first speaker that Gail and Gwen have.

(A ten minute recess was held off the record, and the proceeding was resumed as follows:)

MS. KATZ: I think we have one of our speakers invisible, but on the phone, and I will ask Aaron Gilson to go first and Dr. Heit to follow.

Aaron Gilson, our invisible person, is in Wisconsin. You have his slides in front of you. It is the packet called research findings relative to the efficacy of PMPs in other states. Aaron is part of the pain and policies studies group and you can see its pedigree written very clearly on the first sheet. With that, I am going to turn it over to Aaron.

(Telephonic presentation.)

DR. GILSON: Hi everyone. I have what was transpired up to this time and in order to get an idea what the problem is in your state and how to effectively correct it. I also want to thank you for the opportunity to talk to you. Unfortunately, I can't see your faces and this is not my ideal method of presenting. Throughout my short talk I will make this short giving the limited amount of time. If you have any questions or comments you would like to address, please just let me know. I am skipping quickly from the first title slide to the second slide called Prescription Monitoring Program. Historically, research began when prescription monitoring programs were characterized by the use of government-issued serialized

prescription forms, which is why they were usually referred to as multiple copy prescription forms. These forms were generally only applied to Schedule II medications. With New York they would have another medication that they wanted to monitor within their state. They were generally administered by law enforcement, what was typically a law enforcement tool and rarely used as a clinical tool. In fact, I have been to Sacramento and have seen a room within a building that still houses unevaluated prescriptions in California that were issued in the last fifty years. So that really, in my mind, undermines the utility as a diversion control or abuse control method.

Multiple copy prescription programs associated with a decreased prescribing/availability of Schedule II medications, this was -- had been referred to already this morning. This has been termed the "chilling effect" and stigmatized these medications as well as the practitioners that use these medications. There was an increase in the prescribing and use of medication that weren't covered by prescription monitoring programs. So practitioners avoided the additional responsibility of a prescription monitoring

program when they were focused only on Schedule II. There was a demonstrated cost savings and unfortunately one of the primary pieces of evidence for the effectiveness of these programs on reducing abuse and diversion was, in fact, the decrease in prescribing these medications. That in my mind is not a convincing outcome as there could be a lot of other reasons why there was a use and there were other clinical indications for the use. So there wasn't really any direct evidence of decrease in abuse and diversion as a result of these programs.

I do have to say the use of multiple copy prescription forms, in my mind, would be useful to reduce causing an alteration. And in fact, some states currently use security forms that aren't triplicate, but they can offer more than Schedule II's and serve that same purpose.

Prescription Monitoring Programs are characterized now by use of electronic data transfer systems, which applies to multiple schedules of medications. Therefore, there is a less chance for stigmatization or the substitution effect because there are no other medications to be used alternatively.

Then there is an increase in the administration by helping pharmacies in the state so they move from being largely a law enforcement tool to both a law enforcement and a clinical factor tool, so physicians can access the data to form their treatment and effectively address behaviors of patients they find doctor shopping or going to multiple pharmacies.

The legislation and regulations that implement these programs typically have very clear statements that these programs aren't meant to hinder patient care and that justifies that principle of balance mentioned appropriately. They are recognizing it as an important drug control tool but there is an objective to lessen their impact on legitimate patient care and access to these medications.

Data are compiled in a more timely manner. (Inaudible) California is trying to find the funds to make their program real time. Again, there is little evidence on the prescribing but there is some indication on decreased diversion through reduced investigation time, especially in California officials' statements that diversion moves out of state and that was also touched upon this morning. There's

an immediate need for programs to communicate with one another so that patient activity can be monitored across state lines.

There is that squeezing of a balloon. If you implement a drug control program in one state and those who are seeking drugs for illegal use will tend to find them elsewhere.

The next slide shows reports from Federal Programs. This is meant to be a comprehensive list to give you an idea of the history of the Federal Government. I do have to say that most of these reports, like I implied stated clearly before, tended to use as an outcome measure a decrease in prescribing of Schedule II medications.

The next slide shows similarly a corresponding interest in National Programs like the AMA and National Institute on Drug Abuse. We talk about or issue reports that deal with the characteristics of these programs.

The next slide shows that, perhaps, not surprisingly, there's a great number of reports generated by states that have enacted such programs. Again, you might want to know that. Their report is over a hundred pages and

that is a pretty comprehensively detailed program to the extent to whether the programs are utilized and the satisfaction that practitioners and law enforcement have with these programs. I do have faith that these reports had not to really document how effective their program is in dealing with the diversion issue in terms of explicit metrix related to doctor shopping. I know there are some movements to capture this information but historically this has not been easy to empirically demonstrate.

The next slide gets to the principle and purpose of my talk, Effects of PMPs: Empirical Publications. These are articles that have been published in journals and date back as far 1984. There are only ten empirical studies that look at the effectiveness of these programs. Interestingly, seven of these ten relate specifically to the impact on the triplicate program, so there is a very limited generalized ability, I believe, of these articles.

The next slide shows what I conceptualize as the first generation and second generation articles. The first generation articles are primarily descriptive in nature and they relate to data trends that are divided between prior

program adoption and the time frame subsequent to adoption. All of these articles show a decrease after the prescription monitoring program was implemented with a substitution effect evident.

The next slide is what you were often presented in these articles, graphs like this, from the article which compared Pennsylvania in 1988 and 1989, which didn't have a PMP, with New York's implemented PMP, and of course, there was a decrease with no change of prescribing in Pennsylvania because there wasn't a program.

The next slide is the second generation deals with multi-barrier applications. The 1996 article which I considered to be an article (inaudible) it was the first article to when comparing states with and without multiple copy prescription forms that there was, in fact, significantly a decrease of prescribing these medications across the state, every state that had a multiple copy prescription forms.

The second generation article largely confirmed results from the more simple (inaudible.) I also want to focus on the second and third articles from the bottom,

which in 2004, were the first to examine methods related primarily to pharmacy shopping. In fact, these were the first to show that New York state triplicate program tended to decrease pharmacy shopping, as well as a prescribing of these medications leading to a substitution. They did have a directly evident impact on some metric related to drug diversion and abuse, but that was it and there has been nothing afterwards, at least published at this time.

So if we jump to the next slide, which is really an attempt that I want to make to show some coming out of the University of California, which I am honored to be a part of by Dr. Barth Wisely and Dr. Scott Fishman. We are trying to look at the largest prescription monitoring programs. It is also the oldest prescription monitoring program in existence since 1940, and what these researchers did was work with the Office of the Attorney General in California to receive the data. They found within a 108 month period of Schedule II prescription data and 36 month of Schedule III prescription data that is when the system began collecting Schedule III prescription data. There were roughly 61 million written prescription for 12.5 million patients which is quite an

interesting finding. There is the multivariate methodology for various time frames to identify the prevalence of the substitution effect, identify prevalence of multiple provider episodes and profile multiple provider episodes. This is trying to really quantify a time to a person seeing two physicians for a controlling substance versus those would be five or ten or twelve. So we want to get a handle on what that really means and how do we operationalize that.

The conclusions form the Empirical Work is that PMP can be an important mechanism to reduce abuse and diversion of prescription medications. Immediate and sometimes prolonged reduction in prescribing and availability, appropriate versus inappropriate prescribing. Identify physician and pharmacy shoppers. Reduce the treatment of admissions and importance of proactive reports, readily access to information.

The future efforts are to increase evaluation of PMP's impacts. To enhance practitioners' awareness of electronic PMPs. Enhance the real-time capability and a need to exchange information. It is important to access utility of Advisory Committees, appropriate versus

inappropriate treatment and the affordability in the current economic environment.

In closing, I didn't hear anything this morning about what mechanisms to test outcomes, how you assess the effectiveness of Maryland's prescription monitoring program. I want to state these programs are important to control, you know, the suicidal consequences of drugs. Even as Attorney General Curran said this morning a problem is in obtaining these medications through pharmacy theft. I think that it is an important thing to consider when discussing the potential impact of the prescription monitoring program to what extent has Maryland identified the source of diversions are leading to this problem and how to identify those sources. (Inaudible) I think there's a need to enhance practitioner awareness. I think all these things will help us understand how to best utilize the prescription monitoring program for drug diversion, which I think we are all concerned about.

MS. KATZ: Thank you, Aaron. I think it might make sense to move onto Dr. Heit. We also have a patient that we would definitely like to hear from. I am editing as we are

going along in deference to time.

DR. HEIT: Thank you, Gail, for inviting me to this meeting. My name is Howard Heit and I am a practitioner in Northern Virginia. I think it is important for me to tell the folks on this committee how I got into pain management medicine. You are seeing me in my fourth life. My first life I was in my adulthood and attended the University of Pittsburgh. I was completely in a fog until I met my wife and she domesticated me and introduced me to the finer things in life. My second life was as a Board Certified Gastroenterologist and Hepatologist and I was formerly Assistant Chief of GI at Walter Reed Army Medical Center in their GI department for Walter Reed in the Eastern United States. I came into private practice in Northern Virginia and I was Chief of the Endoscopy Lab at Fairfax Hospital, which is over a thousand-bed hospital, part of Georgetown University.

However, my third life began on 1986, March 28th, 8:15 at night. I was going to the NIH for a journal club. A young fellow was speeding, hit me head-on in a car crash which gave me a very rare muscle disorder called spasmodic

torticollis that put me in a wheel chair for twenty plus years, made me a chronic pain patient.

In my wonderings of going to see various doctors and not sitting in my usual and customary chairs, it became very apparent to me that my fellow physicians had little or no knowledge of pain management and even less knowledge about the disease of addiction and how to treat it. This was a call to action to me, as a pain patient, as a physician, as a husband, as a father, to learn this particular subject.

My particular condition put me in a wheel chair and the fact I had constant muscle spasms, muscle spasms with every movement, were quite severe. At one time, my neck size was 23 and I went down to 170 pounds and that was my birth weight was my 170 pounds.

My fourth life fortunately began on December, 2007 when I underwent deep brain stimulation at the University of Virginia and had a result beyond my wildest dreams that allowed me to give my brace away and give my wheelchairs away to AMVETS and sit here before you.

I have a practice in Northern Virginia. I have a

quite unusual practice. My patient population consists of patients that have pain only, to the best of my knowledge, people who have the disease of addiction only without pain and I will see the most complex patient, the patient that has both pain and addiction if he or she is willing to work a program for recovery for both diagnoses.

So I have to have a risk management program for my practice. I am seeing the high risk patients. The term now we are using is REMS programs, risk, evaluation, mitigation, strategies and I want to go over tools in my tool box to do chronic pain management in patients with or without the history of the disease of addiction, so that you get an idea of what I need to do and what my fellow physicians need to do in order to appropriately give this balance. The balance we talked about was very nicely written up by Aaron and his colleague, Dave Jorsen, the balance to get the medicines to people who need them. So you have the medicines available for research and also the balance to protect the misuse of these medications. That is the delicate balance we are talking about today.

So one of the things that I use in my practice is

called universal precautions in pain medicine and that is a manuscript that I published with my colleague in Toronto that is also about pain and addiction, Dr. Gourley. The term universal precautions originated from the infectious disease model. Back in the late '70s and '80s the health care profession was faced with a dilemma. It was the start of the known HIV, AIDS, hepatitis B, Hepatitis C and how does the physician protect himself, his staff, his family and his community from the spread of infectious disease. Out of this group, the OSHA regulations were widely successful, meaning that every physician has a red bag in his office, which he and she puts biological material which could be hazardous so it is safely stored away or that you gown and glove appropriately when handling a certain biological material.

OSHA laws were very, very successful of containing infection. So Dr. Gourley and I took this conception and applied it to pain management and we had the universal precautions originated, as I stated, from the infectious disease model and a careful ten point assessment of all persistent pain patients within a bio psycho social model.

I emphasize within a bio psycho social model.

Appropriate boundary settings for the patient before writing the first prescription and a triage scheme for risks and referral. We felt by using universal precautions, by using this approach with the pain patient, stigmas could be reduced and patient care could be improved and overall risk of pain management could be reduced.

There are ten principles of universal precautions in pain medicine. Dr. Gourley calls them the ten principles. I am Jewish with a beard and I call them the Ten Commandments.

Number one, a diagnosis with the appropriate differential. As I go through these ten points, please remember that universal precautions is not about the molecules, not about opioids, it is about good medical care of chronic medical conditions. So these principles could be applied to anybody you are taking care of who has a chronic medical condition.

Number two, a psychological assessment of the risk of addictive disorders or co-morbid conditions. You give a person a bath of opioids and unless you address their

anxiety, depression, bipolar disease, history of sexual abuse, physical abuse, you will always fall short of your goals for the particular patient.

Informed consent and a treatment agreement. A treatment agreement is usually written and simply states what I will do for you and what you will do for me based on mutual trust and honesty and sets up the boundaries of each of our responsibilities in regards to me prescribing a controlled substance or the pharmacist dispensing the controlled substance. It's the responsibility of both parties.

A pre-imposed intervention assessment of pain level and function. I'd ask any of the physicians in this office, would any of you prescribe a hypertensive medication without doing a blood pressure first? Would any of you start insulin without doing a fasting glucose or a hemoglobin A1C and why would you start a controlled substance unless you have some evaluation of where the patient is. Is he at zero, no pain, or has the worst pain imaginable. Patient pain rating, your functional goals, what they hope to get out of good pain management.

Number six, an appropriate trial of opiate therapy, and notice I said an appropriate trial and not a God given right. Once it is started and continues if the patient is not reaching his or her functional goals. So one of the clinical perils out of universal precautions I think that has to be taught to the healthcare profession is if you have an entrance strategy for prescribing a controlled substance, you must have an exit strategy if that medicine is no longer helpful to that particular patient or if that medicine is being misused or diverted from the patient.

Number seven, you want to constantly reassess the pain scores and level of function, regularly access the four A's, which are published by Steve Hassick of analgesic/analgesic relief, anti-inflammatory, antipyretic, anticoagulant, zero to ten, are you getting closer to zero. The literature clearly shows if you reduce the patient's pain by thirty-to-forty percent, you markedly increase their quality of life. You have to set up realistic expectations with your patients. Very rarely can I reduce your chronic pain down to zero, other than putting you under a general anesthetic and then your function is going to go way down.

The purpose of good pain management is to decrease pain, increase function and minimize the side effects of the medicines you are going to be using. You periodically review the pain diagnosis including addictive disorders at each visit and last but not need least for the lawyers in our committee here is document in your chart. Document, document, document in your chart. If it is not documented in your medical, legal record, it's a figment of your imagination.

I do a lot of lecturing around the country and one of the common questions is, ghee, my patient came in and was chewing controlled released Oxycodone and I couldn't possibly put that in my record. I say you absolutely put that in your record. The question medically, legally is what you do with that information. Does that mean that patient is disqualified from that molecule. You don't abandon the patient, you may not prescribe them the molecule. You may get them into a substance abuse program. You may say you still need the opiate but then I have to tighten the boundaries and see you more often and get the appropriate healthcare professional into the clinical

picture and expand the treatment team.

The question is, what do you do with that information? It's the same as getting an x-ray and there's an abnormality on the x-ray and you don't do anything with that. The key is what you do with that information.

As I said in my past life I was a gastroenterologist. I have done thousands of colonoscopies and having a colonic perforation is not malpractice. It is an accepted complication, although rare of colonoscopy. Me not recognizing the perforation and doing my due diligence after the perforation, that is malpractice.

The second part of universal precaution is a triage scheme in regard to assessing risks over time. Is there risks in prescribing a controlled substance. If the patient has a breathe, there's a risk. The next question you have to ask yourself is can that risk be managed and the overwhelming majority of the cases the answer is absolutely yes, because we are dealing with good patients who have complex medical problems, not bad patients who have complex medical problems. The overwhelming majority of time the risks can be managed, but who should be your patient and who

should you take care of? It is really based on your education and your comfort level.

Group one in the triage scheme, we feel can be taken care of by the primary care doctor. The person who has chronic pain, who does not have a co-morbid condition or history of addiction, either active or in recovery or doesn't have a psychiatric problem at all, that can be taken care of by the primary care doctor or internist.

Group two is the patient who might be in recovery from the disease of addiction or might have a co-morbid condition or psychiatric disorder and that patient you may want to get a consult and have the patient co managed with you or have the patient's game plan or treatment plan reviewed every four or six months by that consultant, a collaborative effort.

Group three are the specially-care patients, the internist should not touch with a ten foot pole. That is my patient. The patient who comes in and has chronic pain and has an active history of addiction or untreated psychiatric co-morbidity, that is my patient.

So everybody who sees a patient, whether you are

seeing someone for a cardiac problem or pulmonary problem, you always have to ascertain what are you comfortable taking care of based on your education and your comfort level. You always have to ask who is your patient, who is our patient and who is my patient.

I believe part of this management program should also include patient drug testing. That is a consented diagnostic test for full explanation and benefit to the patient. It is not chain of custody or observe unit. It is provide objective documentation and compliance with a mutuality agreed upon treatment plan with urines appropriately negative and appropriately positive. I do urine testing for every new patient that comes to my practice and depending upon their clinical status, will determine the frequency of future random urine tests. That allows me to aid in the diagnosis of the treatment of drug addiction or drug abuse. Again, it will not negate the patient's pain problem but it will bring another diagnosis to light. I made clear to the patient, I can treat acute pain in the face of an active addiction, but I can't treat chronic pain in the face of an active addiction. The

patient has to be willing to work a program for both.

Example, if a patient has cocaine in their urine, I bring the patient into my office and I said I make two additional diagnoses. One, the minor diagnosis of cocaine misuse or addiction. Notice I said the minor diagnosis but I made a major diagnosis of an honesty problem. Unless we solve the honesty problem, how in the world can I prescribe you a controlled substance. Me prescribing you the controlled substance is a privilege not a right. The pharmacist dispensing the controlled substance is a privilege, not a right. The patient receiving the controlled substance is a privilege and not a right. With that privilege comes responsibilities of all parties involved.

Most of the time the urine drug tests allow me to advocate for my patients in legal situations such as divorce, Worker's Compensation, Social Security Disability, which I can write a letter to whatever party that the patient asks me to that the patient is a valid pain patient. They are physically dependent on the medication. They are not addicted to the medication and I emphasize that there's

a major difference between the two. The urine drug test is a measure in order for me to document something objective in my chart for the subjective complaint of pain.

I want to turn to the prescription monitoring plan and I don't want to be redundant but we know that it is active in a little bit less than forty states at this time. For me, with Virginia, I think they have a reasonable prescription monitoring plan. I access that for all my new patients. I essentially do it for all my patients twice a year. It is reassuring to me that if the plan documents that I am the only prescriber of a certain controlled substance. Aaron also pointed out if there is a physician on that list that I am not familiar with I have to bring in the patient and ascertain where they got that prescription from. The overwhelming majority of time, it's a benign reason. They got it from a dentist, even though in the opiate agreement they signed they shouldn't get a controlled substance from anyone else on the planet, it does happen people are given drugs and they didn't think the dentist was a real doctor, they could get the Vicodin for extensive dental work.

What I am saying is if there is unexpectedly more than one prescriber of a controlled substance which may violate my agreement, the key is I do not kick the patient out of my practice. I use that as an opportunity to bring the patient in and educate the patient and find the motive behind the behavior. What was the motive behind accepting the prescription from another doctor and in the overwhelming majority of cases, it's a benign reason, a correctible reason and has nothing to do with abuse or addiction and nothing to do with aversion. It has to do with education of the patient.

For prescription monitoring plans, what needs to be done, under the best case scenario, all fifty states have to be linked together or at least adjacent states. We live in an area where there is Washington D.C., Maryland, Virginia and it makes no sense to not have these three areas linked together. I do physical exams on my patients with addiction medicine and the last three exams I did, they all have legs and could all walk across the state line and get whatever they want if they know there is easier access.

So we don't want to drive the patient from one

state to the other. I think at some point we have the technology to link these states together and realtime results are necessary. It doesn't help me to get results two or three weeks later. Data needs to be studied. Does it reduce misuse and diversion of a controlled substance? Does it reduce the disease of addiction and controlled substance and diversion? Does it reduce death secondary to misuse of controlled substance and more importantly, does it improve patient care secondary to the undertreatment of pain. We have to understand fifty million Americans do not have access to good pain management. Thirty-to-forty percent of people with terminal illness die in needless suffering secondary to inadequate pain management.

Lastly, we have to see whether this is cost effective. One of the questions we have to ask is as a private doctor, I am a target. I am not moving. My patients possible with addiction are set up on street corners and move from corner to corner. Everyone knows where I live. They know where I live, where my office is, I am ten minutes. I am a possible target in this area. The question I want answered as a primary care doctor, as a

person treating pain and addiction with prescription monitoring plan, what percentage of diversion of medicine is coming from script doctors, which I want to put out of business. What percentage is coming from lack of education in regards to doing pain management and what percent is from theft or taking it from mom and dad's medicine cabinet or the internet or counterfeit. We have to know the physician is probably at least ten-to-fifteen percent is from physician. We don't know from those ten-to-fifteen percent of physicians are script doctors and probably less than one or two percent are script doctors as opposed to the rest. The key as we go forward in my long, strong opinion we have to go for education, not regulation. One of the areas states have to push whether it be the University of Maryland, medical schools, is if we take the absolute fact that pain is the most common presentation to a doctor's office, if we take the disease of addiction is ten percent of the population, meaning if this room is representative of the general population, ten percent of people in this room have the disease of addiction. Ten percent of patient in my practice have the disease of addiction. Ten percent of all

patients coming into my practice have the disease of addiction. Why isn't the interface of pain and addiction part of the core curriculum of the training of every health care professional, meaning doctors, nurses, nurse practitioners and that is where we reduce diversion and take better care of our patients through education, not regulation. Thank you.

MS. KATZ: Thank you, very much. Again, unless someone has a very pressing question, we are going to move onto the third person who is actually, physically in the room.

MS. HERMAN: Lisa has agreed to speak with everybody today. She has attended the Health Counsel Support Group where she met Mary French who is the leader there. Lisa, do you feel comfortable coming up?

MS. SPOFFORD: Hi, my name is Lisa Spofford and I have been on disability for two and a half years. I am a licensed social worker clinical, LCSWC, and prior to becoming disabled I had spent a lot of time in the company of individuals who suffered with addiction. I was a social worker in the child welfare system for six years and almost

every parent I worked with had a substance abuse problem.

For the past seven years, I worked with individuals in Maryland Medicaid System with rare and expensive health conditions and sometimes came up against substance abuse issues there, as well.

In August of 2006, I took disability leave from work to have carpal tunnel surgery to correct carpal tunnel syndrome in my right hand. Unfortunately, instead of improving, my hand got progressively worse and worse and worse after the surgery. It took quite a long time to get a diagnosis, actually three months. I had lost my job before I was officially diagnosed with complex regional pain syndrome. I went to -- the first pain management specialist I went to took urine from me and refused to do a ganglion block to treat me for complex regional pain syndrome because I did not evidence all of the symptoms of that particular disorder. He did, however, prescribe methadone for my pain.

Up until that point, I have been more or less suffering through a lot of the pain trying to take over-the-counter pain medications. I had been prescribed Darvocet after the surgery and I had been avoiding taking

it. I didn't want to take that for too long.

So this doctor gave me a prescription for methadone which scared me. I went home and researched it and determined it was actually used for pain and then I did start taking it. I found another pain management doctor, who immediately diagnosed me with complex regional pain syndrome and immediately treating me with ganglion blocks to treat my pain. I experienced some minimal success, however, my pain actually spread from my hands up through my arms to my feet up through my legs.

After about nine months or six months of pretty regular treatments they were no longer effective. During that time also, I did hyperbaric treatment and I was evaluated by a doctor assigned through Workman's Compensation insurance, who stated that there was nothing wrong with me other than I had a pain management problems and I was a methadone addict.

This was really devastating to me because addiction was one of my biggest fears as I was going through this process. I was terrified of becoming addicted, especially taking methadone because I had seen babies addicted to

methadone and seen them going through withdrawal. Just in so much discomfort, and I didn't want that to be me. Then to have a doctor who didn't actually evaluate me for addiction at all, put in writing that I was an addict was devastating and I went to my pain management doctor and requested that I be prescribed some other type of pain management. He did prescribe me Ultram which all of my doctors up to that point insisted it is non narcotic. I know it is actually not but relatively -- I just managed with that. I live with a lot a lot of pain but I wasn't willing to go back.

Not long after that the pain management doctor told me he didn't feel he could do anything more for me. He didn't feel that my pain at that point warranted surgery and he had no other answers. So his solution was I take pain medicine for the rest of my life, which made me really uncomfortable. So I went to see another pain management specialist who was really concentrating on chronic regional pain syndrome and he disagreed. He didn't feel that anyone should just take pain medicine and risk addiction when there treatments out there. We tried several different kinds of

blocks, none of which worked, and than began the process of evaluating me for a neurostimulator.

And on September 11, 2008, I had neurostimulator implants in my neck and lower spine to cover the pain that I was experiencing that was making it difficult for me to walk and use my right arm at all or even to stand up and to do anything and the function level for my life was pretty low.

I had the surgery and it helped a little, not as much as I had been hoping for but unfortunately I developed fibromyalgia following my surgery, which the rheumatologist who I have seen said that happens. So I replaced some of the pain that I was experiencing in my lower extremities that was being controlled by the stimulator with joint and muscle pain and I am still having difficulty walking. My hand pain is not as well controlled by the stimulators. I have back pain now and I am exhausted all the time. I am still not functional and I just want to sleep. I have tried so hard since the surgery not to take any pain medication because that is the whole reason I had surgery so I wouldn't have to take any medication anymore but I can't -- I just hurt too much. If I want any kind of quality of life I have

to have some pain relief.

At this point, I am still taking Ultram, which only gives me a certain level of relief but this is going to be my life I don't want to live it addicted to narcotics and that is it.

The idea of someone monitoring the medications I take would make me more self-conscious about taking it to be completely honest. It's hard enough for me to still think about that document that is out there that says I am an addict and that impacted the assessments that were made of me by my disability insurance and it took a long time for them to acknowledge my CRS because of that doctor, which put my benefits at risk for a while. I don't know, that is my story, I guess.

MS. KATZ: Thank you, very, very much. I know it was difficult and we appreciate it. Gwen and myself felt it was extraordinarily important that this group hear from a really dramatically ill patient, someone who truly suffers from chronic pain and we all were wrapped listening to your story.

One of the things it points out is how difficult it

is for a patient such as you to find a doctor, to keep trotting around from one pain management specialist to another and it was very interesting to watch Howard's face throughout this, as well. These are the patients that you know are out there that frequently are not getting the best advice and then to have them become aware also of a PMP that may or may not be threatening to them. Yet again, it's another layer, another issue, that patients, as well as physicians, have to consider particularly in a case such as this. That was our purpose in asking you to tell your story and we so appreciate you taking the time.

MS. SPOFFORD: Can I just add the first doctor I went to see took my urine and when they prescribed me methadone he made me sign this contract that I wouldn't get anyone else to prescribe me any drugs as long as I came to him and every time I came I would provide urine. I was absolutely mortified.

DR. HEIT: I don't think the physician explained to you the purpose, in other words, I with Dr. Gourley have the infinitive publications and the literature, it's patient centered urine drug testing. It is like me doing a fasting

glucose to evaluate you. In other words, generally speaking, in the high ninety percentile a urine test allows me to support you as a valid pain patient. With the information you gave to me, and again, without sitting down with you, every patient comes into my office gets a copy of a consensus document of a committee I helped form between the American Pain Society, American Academy of Pain Medicine and American Society of Addiction Medicine and the definitions of addiction, physical dependence and tolerance.

I doubt very much whether you have the disease of addiction. I doubt very much whether you will get the disease of addiction, even if I gave you a bath of opioids. Would you become physically dependent, that is opiate specific, or could you get physically dependent on certain antidepressants, beta blockers, calcium channel blockers, steroids for asthma. So the point being it is education of why.

I have, in all of my years of practice, had one patient say I don't want to do a urine drug test because I explained the purpose of a urine drug test and where this purpose would come in is exactly in your situation. As your

physician, if I got that report back from that evaluating doctor that misdiagnosed you, I would insist based on the information that I had in my chart with the opiate agreement, a patient centered opiate agreement, I would insist by letter, under the threat of legal action, with your permission, that that report be amended and corrected. That you do not have the disease of addiction.

I would use all of this information that possibly without education you thought was negative as a positive especially on your part to help defend you with my dying breath and Social Security and Workman's Compensation and you said as objective evidence of you being a valid pain patient, taking a valid medicine for a valid reason, issuing a legitimate medical prescription, using my usual and customary activity, which is quoting federal regulation to help improve your quality of life. What I am saying is that things can be used for good or evil. It depends upon the education and the exclamation. I think if you have the proper education of why the doctor was doing this and why I am assuming they were doing it in a way a patient is centered, got you, and if I got you and I will kick you out.

You never kick a patient out simply because their urine.

DR. FARHA: Do you recall what dose of methadone you were on?

MR. GILSON: It is not really so much the idea of information being out there, it is how that is used.

DR. HEIT: Absolutely.

MR. GILSON: I think that is what all of us are concerned about.

DR. HEIT: There is a lot of information out there, the question is what do you do with it? What you do with that information, and again with the information, even if it is negative information, I want to know what the motivation is behind that behavior before I make any conclusion with that patient. I use things that go wrong in my practice with my patients to increase the communication with a patient to increase the education to solve the problem.

MR. GILSON: Most of you are aware around the table, Howard is a unique physician. The knowledge he has is not shared by many others and we know from research that a lot of physicians who are practicing report a misunderstanding of what addiction is.

DR. FARHA: That is the point I want to bring. A diagnosis of addiction is based on four criteria and that is probably what led him or did not lead him to do the proper diagnosis. There's a difference between physical dependence on medication such as methadone and actually the disease of addiction. I would like to ask you if you recall the dose of methadone you were on?

MS. SPOFFORD: I was on 2.5 to 5 milligrams every four hours.

DR. FARHA: Methadone --

MS. SPOFFORD: Four times a day.

DR. FARHA: So you were on ten milligrams a day and he called you an addict?

MS. SPOFFORD: The conversation went as such: I said -- he asked me about going back to work and I said I couldn't process while I was under the influence of this medication. It was not ethical. My mind is like swiss cheese and I couldn't do what I needed to do and it still is. He said, have you ever tried to get off and I said yes, I have tried but I can't. I was referring to my pain control and he took that to mean that I was addicted.

DR. LYLES: You are the product of a failed system.

DR. HEIT: You did not fail, the system failed you.

DR. LYLES: And this is typical of a Workman's Comp situation. We deal with the pain management everyday. Like Howard said, you have to have some advocacy for your patient. In the case that you had with an IME, this is typical of an IME. I get ten IME's a week. I have to get on the phone and talk to the IME and educate the IME and they will amend the report. You don't have to go to court and all this other stuff. You want to do it in your community. They will amend your report and the purpose is to restore your benefits. You are the grease that makes the Workman's Comp system work.

MS. SPOFFORD: I never got Workman's Comp.

DR. LYLES: You have a judge, multiple physicians and attorneys and they are all living off of you, that is the system we have with Workman's Comp. You are a product of a failed system. Fortunately and hopefully, you are going to find someone that is going to be your advocate and help you take care of yourself.

MS. HERMAN: Just by saying that, hopefully, you

will find somebody, is a disgrace. There are seventy-five million people that have chronic pain.

DR. LYLES: It is not a disgrace.

MS. HERMAN: It is.

DR. LYLES: She has a very difficult problem to treat.

MS. HERMAN: Most people who have chronic pain have a difficult problem.

DR. LYLES: Most people that come to me have undiagnosed physiologic symptoms that somehow have to be put together and it may take me two or three or maybe six months but eventually you stumble onto it.

DR. HEIT: Let me make one statement that is extremely important and topical. DSM4 now is in the process of going to DSM5. If you look at the section of substance dependency and the seven criteria, in Yiddish it's all meshuga (phonetic) and Dr. Charles O'Brien asked my to facilitate letters from the American Academy of Pain Medicine in support of changing the DSM substance dependency to substance addiction and call it what it is so there is not this confusion between addiction and physical

dependence.

In the next issue of Pain Medicine I will have a manuscript again with my writing partner in Toronto going over why it is mandatory this change take place in regard to DSM4 and DSM5 so somebody who does not have this disease of addiction, I am sure without even talking to you, just by the virtue that I have been in medicine for a long time, that you haven't lost control of your medicine. You have not had cravings for your medicine. You know, use the medicine despite negative affects. What you wanted was pain relief. You were pain relief seeking, not drug seeking.

DR. WOLF: I think the point needs to be made is that in her professional experience and personal experience needs to be validated with the fact the data is out there. Our recent experience of what happened in Virginia is not a matter of who has access to the data and how the data is properly accessed. It is the fact it is out there and there are people that have nefarious reasons or what other reasons that are outside of the system or aside of whatever we set up that are going to get their hands on that data. It can't be the ten thousand pound elephant in the room swept under

the rug.

DR. HEIT: Well that is where the DEA gives the proposal that in ten years they want all prescriptions to be done electronically. My question to the DEA is if once you hack into that system you have a gold mine as to the prescription pad being lost by a physician then you have a nugget. There is nothing that is going to be a perfect system. We have to do the best we can so we can provide the care our patients need and deserve and the education of the health care professional.

I am very up front with patients. For me to write rational pharmacal therapy at this point in my life gives the IQ of a plant life. I have to explain the art of medicine with the patient and educate them in regards to what are the definitions and what I can do and can't do and what is the reality of the situation so we become partners. I want a doctor/patient relationship, but I want a teacher/student relationship with my patients.

MS. DAVID: I keep hearing that -- the PMP it will limit the understanding of medication --

(Inaudible.)

DR. FARHA: The threshold is such that unless you had five scripts, attended five different pharmacies and five different doctors, the PMP is not going to pick you out as a doctor shopper. If we plan this correctly and do it very well and use it from a patient perspective, there's a lot of opportunity to the physicians who are taking care of you to see what medications -- I go on there and said she has never been on Neurontin, is she getting the proper physical therapy, there is so much information and that is why if you are inventing a tool it has to mean something.

MS. DAVID: They will be judge.

DR. FARHA: Why not take it a step further and have a doctor be able to help her with getting the proper medication --

MS. KATZ: You are talking about a full electronic medical record. It is coming.

DR. FARHA: We need to be proactive and take advantage of the results we have so we are not playing catch up.

MS. KATZ: As a chronic pain patient who sees a variety of physicians, I can tell you that I am sometimes

asked questions, when exactly did that happen? What did the CT say? Come on, I have a degree in public health. I am not a physician. I did read the reports but I can't tell you what I assume are the details that are important in making a clinical diagnosis. To rely on patients as we are relied on often by our physicians to be the keepers of our own history so that a physician such as you can get the full picture of the complexity of the patient --

DR. FARHA: What is the dose, how much -- how high --

DR. WOLF: All you have is what prescription was filled.

DR. FARHA: Yes, that is correct. That is a different story between fraud seeking and patient management.

MS. KATZ: I think the point of all of this and Mandy, I don't mean to cut you off at all, we need to be hypersensitive that whatever we create is supportive and protective of patients and not inhibiting of their care and that is the point of a lot of the discussion today.

JUDGE FADER: Ramsay has always stressed, and we

heard it a number of times that once we are through here and once we submit a report we have to go on the road because we have to educate the physicians of the State of Maryland, number one, what is this all about. We somehow have to convince them that many of you may be playing in a field that you are not qualified to play in.

So I think that we have something with the support of the Board of Physicians and the Board of Pharmacists and Med Chi and Pharmacists Association that work to do that we all recognize as important and essential after we get this report.

DR. LYLES: If she was my patient I would have the history of her pharmacy for two years, whoever wrote the prescriptions. I'd get that. I would know if you switched from Prozac to Lexapro and every time I sit with you, who changed you, who did you see that made that change --

MS. KATZ: And why.

DR. LYLES: And why, and that is in my record as probably it is in his, but that is a very time consuming visit and the average physician can't spend that time with you. I want you to understand that a level three visit is

forty-seven dollars and thirty-five cents and there is seventeen dollars of profit in that for the physician.

A young physician cannot afford to treat a patient like her. You have to come to someone like me or him who is well-established, over the years, and can spend the time and effort that you need to transition you through life.

MS. HERMAN: That is the whole concept of that time limit. If you want to spend time with your person and help them in their treatment then you spend that extra time.

DR. WOLF: At the cost of what?

MS. HERMAN: Human nature.

JUDGE FADER: The average individual practitioner in family law and in internal medicine in Maryland is earning on the average of a hundred thirty and a hundred forty thousand a year. They get out of medical school with a hundred fifty thousand dollars worth of debt and they are working fifty-to-sixty hours for that. The insurance companies are squeezing them to death. They just can't do it. They have to put bread on the table and support families and pay off their education debt. The human aspect and money aspect of it with no disrespect to you, that is

not going to work.

What Bob is saying and what Ramsay has said all along, part of our education process is, doctor, you are not doing well by this patient because, number one, you can't spend the time with them, and number two, you don't know what you are doing. We will say that in a more sophisticated type of way. The individual practitioner is not going to be able to do that or he or she is going to go bankrupt.

MS. HERMAN: It depends how they treat people. I have been in certain clinics where they have five-to-six people waiting for that fifteen minute slot. That is not a good practice.

MS. KATZ: I think one of the things that I hope also comes out of this discussion is the fact that patients need to be referred to pain management specialists of which there are not enough. But in the same way, an internist would probably, at some point, say this is a patient whose diabetes I can't control in my practice needs to be referred, it should be the same thing. Unfortunately, that is in very few physicians' minds.

DR. WOLF: It goes beyond that to the fact they all have an opinion, as well. They can have a patient going through something unrelated, having a colonoscopy, and the doctor puts in the report it would be ideal to get this patient off of opioids or off a controlled substance. Or they go to the dermatologist and the dermatologist puts it in the record. It crops up over and over again. The patient gets stigmatized because of that.

MS. SPOFFORD: I would go to doctors and when I was taking methadone and the first thing they would ask me is how long I was using drugs and what kind of narcotics was I using before I started using methadone. It was a real effort to get them to understand the doctor prescribed me methadone because I was in pain.

JUDGE FADER: Well, thank you so very much and Gail and Gwen --

MS. KATZ: Mandy has some comments and we have some written testimony that if we have a few minutes we are going to read it.

JUDGE FADER: I need five minutes to tell you where we go from here and I need ten minutes for Ramsay to tell

you about his great experience with regard to a national meeting he attended and then we are out of here.

MS. DAVID: Good morning, I am Mandy David and I am a physician's assistant for the Comprehensive Sickle Cell Program at Johns Hopkins. So a lot of what I am talking about has been discussed. I thought I was going to be up higher, but I will briefly go over some things.

I think the question that we all have at Hopkins and Sickle Cell is we really are thinking about patient care, as well as sensitivity, as well as the fact of provider services. Also, the adverse effects that deal with the treatment of PMP, the high administration and financial burden throughout the state, as well as increasing the costs for patients and pain management that is limited. When I think back when I got my training and it was from my attending, a hematologist. Where she got her training for pain management is beyond me. In the bill or the study for the PMP, I could be wrong, but is there a clear distinction between pain management specialists and those clinicians that can treat illnesses that cause severe pain? Because under the PMP, I don't have the expertise or I don't have

the scope of a pain management specialist. I believe that I write the highest -- not the highest, but one of the highest amounts of narcotics in Baltimore City. My name is Mandy David and I guaranty every pharmacist knows my name.

I've had pharmacists call me and say your patient walked in here with another doctor on their script and then I have to let them know that is the pain management specialist. So they are questioning the pain management specialist who has the expertise because I am the one who constantly writes. What is the criteria? I have a patient who I write medication for who has the most severe form of sickle cell diagnosis who was misdiagnosed as having a milder form and has severe -- both hips, depressed, fibromyalgia and I have her get this medicine. I have her on Oxycontin, 200 milligrams three times a day, as well as Dilaudid. She takes 160 pills in one week. Her level of funds is minimal, as far as being in the work force. She is awake and alert and her tolerance is very high. Do I fall into the criteria? I've had no real formal training. I can't find formal training because there is no program for physician assistants, no programs for pain management. We

have residency and emergency medicine. I had to learn from a physician and if that physician is not good in pain management, then what happens to my training?

DR. FARHA: I can answer a couple of your questions very quickly. The last Saturday in September the American Society of Addiction Medicine of the Board of Physicians and State Medical Society are putting a course together on appropriate opioid prescribing to give you a lot of powerful tools. It's going to be recorded and available on the web for every physician prescribing in the state being proactive to help you move along and give you education.

We did secure a grant to help us with this, and so the financial amounts that are going to be paid by any practitioner attending is going to be much less than you would normally have to take care of.

MS. KATZ: I have the copies of Dr. Fishman's book and anyone who is interested, as supplies last, please, I don't want to carry them again.

DR. FARHA: There is going to be a course available by web. I will put a segment relevant to Maryland law and you can go to the website and look at Maryland law and the

expectations in the state and move onto the national course to make it practical and useful to help people who want to do this. We are developing the tools you are going to need.

The other issue is what you put in the law and how you write the details. That is the very reason why I felt uncomfortable at the beginning and so grateful to have this platform. We have a chance to write in such a way to get the use out of it. These are very important points you are bringing and why we are meeting.

MS. DAVID: I guess I am going to continue, I agree and appreciate the education that is coming for providers. I spend a lot of time writing prior authorizations. I spend a lot of time -- I have patients -- I keep patients' profiles and if I suspect anything I receive, this one of the best creations for narcotic therapy. It builds trust in patients and it also take away trust from patients, as well. The amount of time I have to document when they have gone to multiple people -- I have patients I see three times a week, three pills here and four pills here. Now it is here and now it is there. The amount of documentation I have to do on top of the prior auth just to get them the pills, as well

as -- we keep a database of every narcotic that I write in the practice. If I have law enforcement or someone breathing down my neck and putting me under a microscope, this is going to add an additional layer. If they determine I do fit the criteria there are still cracks everywhere. If I am writing more and more, being a pain management specialist, I may be looked at or maybe not. I don't want the extra work that it already takes to treat a patient. Do I have to close down a practice because we have eight charts to go through?

This was yesterday, for example, I had four pills, Oxycontin pills, and it said please take one pill every seven days.

JUDGE FADER: One what?

MS. DAVID: Take one pill every seven days. The patient was in the ER. I called them and they said I am concerned, I don't want anyone looking down my throat. We already have the fear of the unwarranted scrutiny.

MR. FRIEDMAN: The provider wrote the prescription that way --

JUDGE FADER: It is never going to eliminate it.

The question is how are we going to cause these occurrences to be minimal?

MS. DAVID: Exactly. For the sake of patient care, I have to track it and it takes time to track down these physicians. I agree that the bill is a public health issue. I do think that --

DR. FARHA: Mandy, last year we disciplined 292 physicians for not meeting the standard of care. Any doctor who writes a prescription for one pill a week of Oxycontin is more of a problem --

JUDGE FADER: When you say you discipline, a great part of that discipline is telling that physician he or she has to get educated and has to correct what they are doing.

DR. FARHA: No, this is much heavier.

JUDGE FADER: You are talking about suspension and revocation?

DR. HEIT: That is wrong, then you are prescribing for the individual's case --

DR. FARHA: If there's an incident or situation they may get an advisory letter. We review the situation and if it is not proper, you should have done this or that,

et cetera. But if you have cases that require much more, that are much more dramatic, we have 292 of those. We have three that were intoxicated that we disciplined. We have seven that were addicted or habit abusers. We have twenty-two that willfully made false reports or records in the practice of medicine. I am talking about narcotic type stuff. We have twenty for the standard of care. We had twenty-one that self-prescribed or gave away administered or for illegal use that were disciplined and these are heavy duty reported cases.

JUDGE FADER: We tell our pharmacists every year that if any pharmacist in the State of Maryland dispenses a prescription written for a CDS by a physician for himself or their family, they deserve every bad problem that is coming their way. We try to discourage that every way possible. The American Medical Association specifically says that is unethical for a physician to write those prescriptions for CDS for himself or his family.

MS. DAVID: How many physicians on the mid level do we have in the State of Maryland?

DR. FARHA: We have twenty-three thousand licensed

physicians. I don't know how many --

DR. LYLES: Seventeen thousand --

DR. WOLF: That doesn't include dentists or podiatry.

DR. FARHA: We have vets and nurse practitioners and --

MS. DAVID: But overall, there are not a lot of physicians abusing the system, correct?

DR. FARHA: That is correct. The system we have right now we don't have too many that we can identify --

DR. LYLES: We see it as the Board using us --

MS. DAVID: Abuse is a strong word.

DR. FARHA: Out of all that are investigating, how many end up doing something about it, how many end up going through the system, in any typical meeting look at the report that you get quarterly --

JUDGE FADER: All right. I am going to ask Gwen if she will read -- you must understand we are trying to keep faith with people to get them out of here at 12:30 to 12:45 at the latest. Gwen has one more thing to say and we have Ramsay's presentation and then I will tell you where we are

with regard to the July 17th meeting.

MS. HERMAN: This is a letter from Beth Murinson, a doctor in Maryland and we wanted to have everyone have a chance to hear from a doctor in Maryland. She is an Assistant Professor Director, Pain Education Department of Neurology Core Faculty, Colleges Advisory Program Nathans College, Johns Hopkins School of Medicine Diplomate, American Board of Psychiatry and Neurology Diplomate, American Board of Pain Medicine.

Before beginning, I would like to indicate that I have no conflicts of interest to report. I receive no pharmaceutical company support. I have received honoraria from national organizations such as the American Academy of Neurology and the American Pain Society, as well as the Veterans Administration Medical System. I am currently writing a book about back pain. My overall career objective is to increase medical students' education in providing world-class pain care, care that is both responsive to the patients' needs and responsible to society.

My comments today are provided in light of the four roles I have. One, I am a treating Maryland physician

responsible for treating a number of patients with intractable pain conditions. Two, I am a medical educator at a medical school in Baltimore dedicated to improving knowledge about pain and pain care. Three, I am a medical researcher, committed to a better understanding of how health care providers make sound medical decisions about pain care. Four, I am a native Marylander and resident of Baltimore City deeply concerned about the well-being of my neighbors as we struggle against the dual scourges of drug addiction and drug-related crime. I am a member of the Maryland Pain Initiative and have been involved in MPI's discussions about the impact of prescription monitoring plans. It is my perception that the MRI Board members are deeply concern about any initiative that might impede better pain care. It has been noted by some that increased scrutiny given to controlled substance prescribing whether through requirements for secure prescription pads, special licensing programs or increased monitoring may have a chilling effect on the treatment of pain.

For the most part, I agree that any program that will decrease the likelihood of a pain patient receiving

appropriately powerful pain medication, when and where needed, is not what our patients need. We have a pain epidemic as clearly documented by the recent Maryland pain survey. Although, opioids and other controlled substances are just one part of the large array of pain treatments that a knowledgeable prescriber can recommend, we are still limited in the number of safe, effective and readily administered medications that are highly potent against pain.

One important reason that Percocet remains the most widely prescribed drug year after year for pain its incredible potency against strong, acute pain. For most people, a short course of oral opioids is the best choice for safe, cost effective pain control. For most people, this treatment will not result in addiction, drug dependence or a life of crime. In my own case after my four-year old son broke his arm, he was in agony when the field-splint was removed for the examination in the hospital. I was grateful for the immediate pain relief provided by the shot of morphine he received, despite my misgivings about exposing him to any potentially harmful substances. He continued

with some codeine elixir at home, which he vehemently refused to continue once the pain subsided stating that he didn't want to take the medicine that made him feel bad. This experience of not liking opioids is echoed by many people but there are those who are willing to pay substantial amounts of money for illegally obtained prescription drugs. It is indisputable prescription drug abuse that is the fastest growing drug problem today. It is young adults who are especially vulnerable. Their important challenges are worthy of the concerted effort that has been put forth by the committee and for that I would like to express my thanks. I'd like to say a resounding thank you to the committee for all of the hard work you have put into this process, and thank you for the opportunity to present my comments. It seems there are many forces at work endeavoring to shape the quality of medical care today. Some of these are acting in the best interest of patients and some of these are driven by potential for economic gain and others are pursuing particularistic agendas. All of these could be invoked in a presentation such as this. I would like to focus my comments on the area that I believe

most strongly impacted by the creation of a Maryland PMP. The thousands of conversations that occurred between patients and doctors, nurses and pharmacists and other providers each day. These conversations lead to decision making by the patient and provider and the decision to determine whether a pain care program will be effective of left wanting.

For this reason, I will assert that the most valuable outcome of a Maryland PMP would be improved patient care in the context of decreased opportunities for controlled drugs to enter the diversion stream. How can this be accomplished?

First, it must be recognized that almost no physician wants to provide drugs for diversion. There is no doubt that doctors must be the first line of defense against diversion. We have all worked mightily for our degrees, our credentials, our positions in society. A PMP that treats physicians as a potentially deviant group will engender hostility and will be very expensive with little effect. The reality is that most doctors who do provide prescriptions that end up in the diversion stream, do so

unwittingly. A PMP that allows physicians to gain information about a patient's history of controlled substance use could be instrumental to minimizing doctor shopping as a cause of drug diversion.

Second, many physicians currently practice medicine in an information vacuum that in the 21st century can only be described as bizarre. We as physicians know little about the cumulative effects of our prescribing, while others around us know all.

As an example, when a physician's prescription is presented to a pharmacy, the prescription data is collected from the pharmacies by free enterprise companies. These companies aggregate the pharmacy data to create a profile of a physician's prescription writing pattern. They then sell this valuable information to pharmaceutical companies among others. The net result is that a pharmaceutical representative, drug rep, walking into a doctor's office can know more about a doctor's prescribing in a crisp analytical fashion than the doctor. A PMP that allowed physicians to monitor their own prescribing would be potentially valuable.

Third, Maryland physicians work at a selective

disadvantage because of the existence of PMP programs in neighboring states. Determined prescription drug abusers will seek out unsuspecting Maryland providers knowing that we don't have the capacity to check up on our patients' prescription filling habits. I, myself, have been subjected to visits from such patients. It is a pitiful waste of valuable healthcare resources to spend time and energy making phone calls to out-of-state pharmacies to determine the reliability of a patient's story. A PMP that can collect data from out-of-state pharmacies is important for a state like Maryland.

Fourth and lastly, patient provider communications can be greatly improved by better access to hard data about prescription use. During my residency, I spent part of three years at a Veteran's Administration Medical Center. Although the VA often gets a bad rap due to long waiting lines, limited access to overstressed resources and a constrained drug formulary, one wonderful benefit of working in a VA is success to the computerized medical record. It is possible with a few key strokes to review all of the notes from other providers, reports of diagnostic tests,

laboratory findings and most importantly, the prescription filling information. This is a wonderful tool for detecting aberrant behavior, patient who act out, lose prescriptions and fill multiple prescriptions for the same problem are readily detected. This is not to say that a veteran can't go outside the system, but it does indicate that having hard data about prescription filling during an office visit greatly facilitates prescription filling during an office visit, greatly facilitates meaningful discussion about the details of a treatment plan. A Maryland PMP should provide data that can be accessed during an office visit. Because addiction is a chronic neurobiological disease, it could be argued that it isn't necessary for the system to have realtime data. In a condition that evolves slowly and persists for years, the effect of having data that is within two weeks of current would be very effective in detecting problem patients.

In conclusion, one of the critical aspects of medical practice today is the quality of the patient/physician relationship. A PMP that provides information to physicians, allows physicians to

self-monitor, gives access to information from other states and is available in the context of an office visit will serve as an invaluable tool to aid in the responsible and responsive treatment of pain.

Thank you for your time. I am happy to answer any questions. My e-mail is bb@jhmi.edu. If anybody has any questions for that.

JUDGE FADER: All right.

MS. KATZ: I would like to remind people about the book.

JUDGE FADER: Anybody who wants a copy of this book, feel free to take it on your way out. Now within the next week or so, Georgette, Michael, John Stant and myself and anyone else here who wants to be part of that meeting, needs to e-mail Georgette and tell her. Michael and Georgette are going to send out an e-mail as to the times. We are going to meet in preparation for the July 17th meeting to put together a format of areas of discussion and information. We will send that out to everyone by July 1st. We hope and we expect that as quickly as possible, anybody can get back to us and say would you put this in here or add

to this or do this or do that, as quickly as you can.

On the 17th of July, we will discuss that format and everything that everyone feels should be injected, such as a paper, a discussion of someone making a presentation here or whatever into that particular topic for discussion.

Again, Michael and Georgette are going to send out e-mails to John and myself as to the times we have available and we'll go down to the State Health Department and meet at Patterson or whatever you want to do. Patterson is better, the parking is free, just a comment. I am on a limited income to do that.

Also, Ramsay, Bob and Marcia and I will meet and I will send out an e-mail the first of next week and anyone that needs to be involved with that needs to tell me. We have some problems as far as pain control that is going to be a specific topic that requires a little bit more. Marcia now has generated a problem -- she has not generated it, she brought our attention to the generation of the problem about insurance companies and the State Medicaid people trying to dictate to her a certain drug that she should use as opposed to what she is prescribing that has a potential for great

harm and I will send out an e-mail by Monday or Tuesday at the latest to ask you about dates and times, probably a breakfast meeting would be better, something of that sort. And anyone who wants to be on let us know.

Before Ramsay tells us -- everybody should have those dates. Do you have the dates? Did you put them on your calendar?

MS. ZOLTANI: It's in the minutes.

JUDGE FADER: That is all that we really have except that Ramsay has had a very, very good experience working around the clock and talking with people at a meeting he just attended. Is there any other business or does anyone want to draw attention to anything before Ramsay talks about that?

MS. ZOLTANI: Approval of the minutes.

JUDGE FADER: Does everyone approve of the minutes of the last meeting? It's unanimous.

MS. BETHMAN: I have a housekeeping. I wasn't able to attend the last meeting and I apologize. In looking over the minutes I see that you sent out the dates for the next four or five --

JUDGE FADER: And asked for comments.

MS. BETHMAN: I wasn't able to comment but I have a conflict with every second Friday. I'd ask for consideration when we get to the work group session. I have a standing board meeting I have had to attend the last ten years.

JUDGE FADER: Did we do those the second Friday?

MS. BETHMAN: Starting in the fall they are on the second Friday. I understand Fridays are great for everyone and that is fine. I can do any other Friday in the month, it is just the second Friday --

JUDGE FADER: Let me get together with Georgette and put something together with regard to that.

DR. FARHA: I had the privilege of attending the Alliance of States for Prescription Drug Monitoring Programs. I was asked by Judge Fader to attend the meeting. This group works under the function of the Harold Rogers Drug Monitoring Program grant, which has been supplied by the Bureau of Justice Assistance. The Bureau of Justice Assistance has been awarded funds toward that and many many other areas.

For two solid days I had a chance to deal directly with programs that have been established and had firsthand experience in learning from many of them, of all of the problems they have faced and how they were trying to assist. And ironically enough for me not having a program here I can see the problems they ran into from lack of information and looking at it in all different natures. This reported a number of changes to do to help in those respective areas.

Needless to say, the program's aware all across the board from very, very criminal investigation standpoint, secrecy and the doctors, hospitals, no one gets information, just strictly a criminal investigation model in Pennsylvania to one that is very educational with no criminal involvement at all and no access to be used criminally. So it's across the board and all of those in betweens.

The one thing that I learned that makes a lot of relevance to what we are doing here is we need to be careful as we are constructing to get the best of both worlds and we can do that. We have to sit down and look at it and really notice what would be wrong to do. (Inaudible) One example was in Virginia where the data was housed in the Health

Department and they didn't have the proper scrutiny in how to put the firewalls instead of some of the others that contractors with companies do that. So unfortunately they are all over the place. We know what we should be looking at.

JUDGE FADER: Gail, Gwen and Mandy, thank you very much. We very much appreciate everything.

DR. FARHA: One thing I feel is critical as we are going with the July 17th agenda is to quickly start now formulating should everything go through where we can get the money. Right now we have NASPAR which has provided up to two hundred thousand dollars as far as funding and granting this. There are certain rules in there. We had a chance to do a recommendation so the rules could be such to start to fit. It's very heavily electronically based and how to get that grant application for that.

The other one which is much more relevant is the one from the Bureau of Justice, four hundred thousand dollars at the stage of where we are now. We missed out an opportunity of a fifty thousand grant. The funds ended --

MS. ZOLTANI: We already put in for it.

DR. FARHA: We have now an opportunity for four hundred thousand.

JUDGE FADER: Don't anybody tell anybody else in the state about this money.

DR. FARHA: This would be a start up, however, we are competing with many other people towards the six million dollars. One thing is that we don't have a program and they do. It is important to do it right now to develop it. There is a lady by the name of Green who did the official model and has some insight in going through some of the areas. I met and connected with Ruby and Rose so we can make sure how to do it. This is going to be critical. That application has to be in in January. It ends in February. So obviously, we have to put in an application contingent that the law is going to get passed. That money won't be available until the following October.

MS. ZOLTANI: The fifty thousand is a planning grant. The second one is an implementation grant. For the second one we can only apply when it is said yes, it has been approved and then we can apply.

DR. FARHA: No. They allow you to apply in January

but they take into consideration because you have to apply before February. They will accept your application, but they are not going to rule on it until July and you won't get the money until October. They all know they have our deadlines and we have our deadlines.

JUDGE FADER: It will be contingent upon the legislature.

DR. LYLES: Department of Health?

MS. ZOLTANI: Department of Justice.

DR. LYLES: No, no. You make the application. Who did you make that through, DHMH?

MS. ZOLTANI: Yes.

DR. LYLES: That is what I was asking you. It's a DHMH request.

MS. ZOLTANI: DHMH, Division of Drug Control. This is a grant through the advisory counsel. I had in there the Department of Health and Mental Hygiene and the Division of Drug Control.

DR. FARHA: There is the ability, if we do it right, to get a lot of subsidy. The key is how to maintain it and where the money is going to come from and how are we

going to move on from there.

MS. ZOLTANI: Just because lots of people apply, they don't all get them.

DR. FARHA: Competitive.

MS. ZOLTANI: Yes, competitive.

JUDGE FADER: One of things may be we are coming in after a lot of other states with the ability to profit from their mistakes and be able to create a very good model and a stepping stone for the people.

DR. FARHA: I have a feeling everybody is going to look at Maryland and say, wow, that is what we want.

JUDGE FADER: One of the big problems in all of this is will my computer talk to your computer.

DR. FARHA: The way it will happen is they are given eighteen months to upgrade from the 2007 platform. Some of them are functioning from a 1987 and 1998 platform. In Maryland we were lucky enough by the time to be implemented in 2010 we (inaudible) it is something for us to look at.

JUDGE FADER: If I don't receive any comments by anyone by July 7th or 8th, I will make an individual phone

call to anybody who hasn't responded because we need your e-mails saying we should consider this report when we talk about this or we need that report or we should consider this testimony and everything and anything under the sun on these topics. When we get to talk about this and we go in and say this is about this topic or that topic we have a pretty good assembly of information with regard to speakers or literature or something of that sort. Thank you all very much.

(The meeting was concluded at 12:41 p.m.)

CERTIFICATE OF NOTARY PUBLIC/REPORTER

STATE OF MARYLAND

COUNTY OF BALTIMORE to wit:

I, Monica A. Sienkiewicz, a Notary Public in and for the State of Maryland, County of Baltimore, do hereby certify that I am not an employee of counsel nor related to counsel or the parties in any way and have no interest in the outcome of this proceeding.

I further certify this transcript of testimony was prepared accurately by me to the best of my ability, knowledge and belief.

As witness my hand and Notarial Seal this 30th day of June, 2009.

Monica A. Sienkiewicz, Notary Public

My Commission expires 10/9/11.